

REMARKS

The claims have been amended to address the issue of missing claim 19 as noted in the Notice of non-compliant amendment dated 1/17/2006. Applicant notes that claim 19 was never added to the application as part of the amendment of October 12, 2004, which added claims 14-18 and 20-24. Thus, Applicant has amended the claims by renumbering claims 20 - 28 to claims 19 - 27. Applicant respectfully submits that this issue is now moot.

Claims 1-3, 5-8, 10, 12, 15-18 and 21-28 are pending in the present application. The Examiner has rejected claims 1-3, 5, 7, 8, 10, 12, 15-18 and 21-24 as being obvious over Purdy (5,527,338) in view of Mebin-Uddin (3,540,431). According to the Examiner, Purdy discloses all of the limitation of the claims except for the attachment means of the plug and the insertion device, and Mebin-Uddin discloses a blood vessel filter with an attachment means and insertion device as claimed.

The applicant has amended the claims to define clearly over Purdy and Mebin-Uddin. In particular, the claimed plug is positioned axially in the lumen of the blood vessel adjacent its severed end and held in place by the wall of the lumen of the blood vessel grasping the occlusion plug. The distal tip, tapered outer surface and large diameter section together define a continuous occluding surface that blocks the flow of blood through the vessel lumen out the severed end of the blood vessel.

In contrast, the expandable device of Purdy is inserted into the vascular system by a deployment catheter. It is ejected from the deployment catheter by pushing on its trailing element, which is positioned distally relative to its expansion members. When deployed, the device expands until the tips of the expansion members contact the vessel wall. Blood clots form on the fabric between the expansion members in order to block the flow of blood through the vessel. FIG. 10 and col. 7, line 31 to col. 8, line 18. Thus, the expandable device of Purdy is not deployed adjacent the severed end of a blood vessel nor is it gripped by the walls of an expanded lumen of a blood vessel. Moreover, the expandable device of Purdy does not include i) attachment means disposed within an interior chamber of the plug, and ii) an inserter device that applies an axial force from a proximal position relative to the rear opening of the plug and the severed end of the blood vessel to insert the plug into the lumen of the blood vessel adjacent its severed end as recited in claim 1.

Mebin-Uddin does not remedy the shortcomings of Purdy. It describes an expandable blood filtering device that is inserted into the vascular system by a deployment catheter. It is ejected from the deployment catheter by manipulation of a guide wire 42 that engages a recess 50 of the filter body. When deployed, the device expands until the tips of the spokes of the filter body contact the vessel wall. Col. 2, line 37 to col. 3, line 37. Thus, the expandable device of Mebin-Uddin is not deployed adjacent the severed end of a blood vessel nor is it gripped by the walls of an expanded lumen of a blood vessel. The expandable device of Mebin-Uddin does not include an inserter device that applies an axial force from a proximal position relative to the rear

opening of the plug and the severed end of the blood vessel to insert the plug into the lumen of the blood vessel adjacent its severed end as recited in claim 1. Finally, the expandable device of Mebin-Uddin employs filtering media supported by a skeletal framework. The filtering media filters blood flowing through the vascular passageway in order to break up clots that may form in the passageway. Thus, the expandable device Mebin-Uddin is used for a very different purpose than occluding blood flood adjacent a severed end of a vessel lumen as recited in the claim.

Moreover, the combination of Purdy and Mebin-Uddin fails to provide a continuous occluding surface as recited in claim 1. In particular, the use of the recess 50 of Mebin-Uddin with the expandable device of Purdy alleged by the Examiner would provide a flow path for blood through the recess 50 and thus would not provide a continuous occluding surface as recited in claim 1, and also would not function to block the flow of blood through the lumen upon insertion therein as recited in the claim.

Moreover, it is well settled that in establishing a *prima facie* case of obviousness under 35 U.S.C. §103, it is incumbent upon the Examiner to provide a reason why one of ordinary skill in the art would have been led to modify the prior art reference or to combine reference teachings to arrive at the claimed invention. Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1385 (Fed. Cir. 2001). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art **and not from the Applicant's disclosure**. Uniroyal, Inc. v. Ridkin-Wiley Corp., 5

U.S.P.Q.2d 1434 (Fed. Cir. 1988). From the above it becomes clear that neither Purdy nor Mebin-Uddin suggest the incentive to combine provided by the Examiner. Rather, the primary reference (Purdy) is inserted by applying axial forces to a distally positioned trailing element which is separate and distinct from the occluding body and thus specifically teaches away from utilizing a structure taught by Mebin-Uddin. Thus, the Examiner has not made out a *prima facie* case of obviousness.

For these reasons, Applicant respectfully submits that independent claim 1 as amended is patentable over the cited prior art. Similar arguments apply to independent claim 7 and renumbered claim 24.

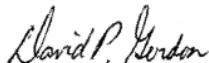
Dependent claims 2-3, 5-6, 8, 10, 12, 15-18, and renumbered dependent claims 20-23 are patentable over the cited prior art for those reasons advanced above with respect to independent claims 1 and 7 from which they respectively depend and for reciting additional features neither taught nor suggested by the cited prior art. For example, claim 7 recites that the plug is made of silicone. Nowhere does the cited prior art teach or suggest this feature.

Finally, it is noted that renumbered claims 24-27 present limitations not found in either Purdy or Mebin-Uddin. Renumbered claim 24 requires a substantially frusto-conical, flexible, non-expanding element having an outer wall with a closed nose, an interior chamber, and a rear opening. Clearly, the Purdy and Mebin-Uddin are expanding devices which do not meet such a limitation. Renumbered claim 25 requires a coupling

element for the plug which is integral with the flexible metal spokes and such a coupling element is not found in the cited art. Renumbered claim 26 requires that the coupling element which is integral with the metal spokes define a pilot hole. To the extent that Mebin-Uddin has a pilot hole, clearly the pilot hole is not part of the metal spoke element.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,



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